## THE UNITED STATES DISTRICT COURT FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

BASF AGRO B.V., ARNHEM (NL), WÄDENSWIL BRANCH, and BAYER S.A.S.,

Plaintiffs,

Civil Action No. 10-cv-274

v.

CHEMINOVA, INC.,

Defendant.

# PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR <u>PRELIMINARY INJUNCTION</u>

BASF Agro B.V., Arnhem (NL), Wädenswil Branch ("BASF"), and Bayer S.A.S., ("Bayer") respectfully submit this memorandum in support of their motion, pursuant to 35 U.S.C. § 283, Fed. R. Civ. P. 65, and LR 65.1, for a preliminary injunction prohibiting defendant Cheminova, Inc. ("Cheminova") from infringing Plaintiffs' United States Patent Nos. 6,414,010, 6,835,743, and 6,620,943.

#### PRELIMINARY STATEMENT

Plaintiffs seek a preliminary injunction to prevent Defendants' imminent infringement of three patents related to the methods of use for Plaintiffs' market-leading termiticide products, Termidor® and PerimeterPlus<sup>TM</sup>, and the manufacturing processes for making their key ingredient, fipronil. Over the last eight years, Plaintiffs have invested millions of dollars to acquire the exclusive right to sell Termidor® and PerimeterPlus<sup>TM</sup>, and spent millions more to improve the products and their manufacturing process, and to build their brand names, customer goodwill, and a network of high quality distributors that provide necessary

customer support. Now, Defendant is taking concrete steps to infringe and has threatened to try to invalidate Plaintiffs' method of use patents unless Plaintiffs give up their legally protected right to be the exclusive seller of fipronil-based termiticides like Termidor® and their methods of use like Perimeter Plus TM. Plaintiffs expect that Defendant, out of commercial necessity, has copied the very same patented methods of using those termiticide products that Plaintiffs spent millions of dollars to acquire, develop, and market. Defendant is also taking steps to sell infringing product that is made in violation of Plaintiffs' manufacturing patent. Absent an injunction, this infringing conduct will begin on or about August 4, 2010, and will strip Plaintiffs of the exclusivity the patent laws are intended to provide. It will also irreparably harm Plaintiffs by destroying their brand reputation, customer goodwill, market share, pricing strategy, and the distribution system that the Plaintiffs have developed and nurtured. Preliminary injunctive relief is appropriate to prevent such harm.

Plaintiffs hold the exclusive right to the country's best-selling and most effective termiticide, Termidor®; its active ingredient, fipronil; and its proprietary, innovative method of use, Perimeter *Plus* TM. The patents at issue cover the pioneering Perimeter *Plus* method for using insecticides containing fipronil, which materially improves efficiency and provides substantial savings of both time and money for end-users, and cover various specialized and complex methods for manufacturing fipronil on a commercial scale.

Defendant has been clear about its intention to enter the market with a copycat termiticide product. In March 2010, Defendant threatened to try to invalidate the method of use patents unless Plaintiffs promptly licensed it to sell a fipronil-based product in the United States. Of course, a license and an attempt to invalidate the use patents would not be necessary unless the Defendant's product offering otherwise infringed Plaintiffs' patents. Defendant also has

confidentially submitted for the Environmental Protection Agency's approval, its own fipronil material, its own fipronil end-use product, and a proposed label containing method of use instructions. When this submission becomes public (or is produced in discovery here), Plaintiffs expect it will show that Defendant has literally copied substantial portions of the method of use instructions from Plaintiffs' pre-existing Master Label for Termidor® and its patented Perimeter Plus<sup>TM</sup> method. Commercial necessity will require Defendant to offer the substantial time and cost savings afforded by the patented Perimeter Plus<sup>TM</sup> method in order to make its product attractive to pest control distributors and end-user customers. As it prepares to enter the market with an infringing product, Defendant also has recently solicited one of Plaintiffs' largest distributor customers for Termidor®, promising to begin selling in the fall of 2010.

Defendant also will infringe Plaintiffs' manufacturing process patent when it begins selling in the United States. The known, cost-effective methods of manufacturing fipronil on a commercial scale are covered by Plaintiffs' patents. Plaintiffs have not been able to learn with certainty which manufacturing process Defendant or Defendant's supplier of fipronil will use, but Plaintiffs believe that Defendant is manufacturing fipronil by a so-called "oxidation route." BASF is not aware of any cost-effective, industrial-scale, oxidation route manufacturing processes for fipronil material that would not infringe Plaintiffs' '943 Patent when the manufactured product is sold or used in the United States.

Plaintiffs respectfully request that the Court enjoin Defendant from selling or offering for sale infringing fipronil-based products before Defendant causes harm that will be irreversible. For the reasons set forth below, (1) Plaintiffs are likely to prevail on the merits of the case; (2) introduction of Defendant's infringing product prior to resolution of this litigation would cause Plaintiffs severe and irreparable harm by materially degrading the value of the

brands they have built and by substantially eroding their market share and pricing; (3) the balance of hardships substantially favors Plaintiffs; and (4) an injunction will promote the public interest.

#### STATEMENT OF FACTS

#### I. The Parties

Plaintiffs. Plaintiffs are both among the world's leading agrochemical product companies. BASF is a company organized under the laws of The Netherlands, acting through its Swiss branch office, which is organized under the laws of Switzerland. (Decl. of Keith A. Holmes in Supp. of Pls.' Mot. for Prelim. Inj. ("Holmes Decl."), Ex. A ¶ 5.) BASF's chemical product portfolio, supported by its intellectual property, focuses on pesticides, herbicides, and insecticides. (*Id.*) Bayer is the owner of two of the patents-in-suit, described below. (*Id.* ¶ 20.)

In a deal signed in 2002 and closed in 2003, BASF purchased from Bayer CropScience AG, for a substantial sum, the business related to fipronil. (*Id.* ¶ 10.) BASF is now the owner or an exclusive licensee of all the fipronil patents, including the patents at issue. (*Id.* ¶¶ 11-12.) BASF markets and sells Termidor® and Perimeter*Plus*<sup>TM</sup> in the United States through its agent, BASF Corporation ("BASF Corp."). (*Id.* ¶ 14.) BASF Corp. operates much of its U.S. fipronil business out of its Agricultural Solutions Division's U.S. Headquarters in Research Triangle Park, North Carolina. (*Id.*)

**Defendant.** Cheminova markets, distributes, and supplies agrochemical products in the United States, including products in competition with Plaintiffs. (*Id.* ¶ 26.) Cheminova's principal place of business is Research Triangle Park, North Carolina, and it is a wholly owned subsidiary of the Danish company Cheminova A/S. (*Id.* ¶ 24.)

#### II. The Patents

There are three patents-in-suit.

The Perimeter Use Patents. Two patents-in-suit relate to innovative methods of using fipronil. These are the '010 and the '743 Patents ("the Perimeter Use Patents"). (Decl. of Dr. Robert W. Davis in Supp. of Pls.' Mot. for Prelim. Inj. ("Davis Decl."), Ex. B ¶¶ 5, 16-19.) They cover applying the insecticide by particular methods along the outside perimeter of a building. (*Id.*) Compared to conventional treatment methods, the patented methods of use save end-users substantial money by materially reducing the quantity of the product used and the time-intensive labor associated with application of the product to the often difficult to reach interior spaces of a building. (*Id.* ¶¶ 5, 9-11.)

The '010 and '743 Patents were issued on July 2, 2002 and December 28, 2004, respectively. ('010 Patent, Ex. G; '743 Patent, Ex. H.) Bayer is the assignee and owner of the Perimeter Use Patents, and BASF is the exclusive licensee of the patents in the U.S. with respect to fipronil. (Holmes Decl., Ex. A ¶¶ 11-12, 20.) Plaintiffs own all rights, title and interest in and to the Perimeter Use Patents. (*Id.* ¶ 20.)

The majority of post-construction termite control treatments performed in the U.S. today use BASF's Termidor® products and follow methods of using termiticide that would infringe the Perimeter Use Patents if done with a non-BASF fipronil-based product, like Defendants are preparing to bring to market. (Holmes Decl., Ex. A ¶ 19; Davis Decl., Ex. B ¶ 12, 16-18.)

The Process Patent. A third patent-in-suit, United States Patent No. 6,620,943 ("the '943 Patent"), was issued on September 16, 2003, and is entitled "Process For Preparing 4-Trifluoromethylsulfinylpyrazole Derivative." ('943 Patent, Ex. E.) The '943 patent teaches and claims novel processes for preparing a class of chemical compounds, including fipronil, from a different class of compounds. (Decl. of Dr. Martin Sukopp in Supp. of Pls.' Mot. for Prelim. Inj.

("Sukopp Decl."), Ex. C ¶¶ 12-13.) The '943 patent teaches and claims the final step in processes to make fipronil. (Sukopp Decl., Ex. C ¶¶ 21-23.) BASF is the assignee and owner the '943 Patent and the holder of all rights, title, and interest in and to the '943 Patent for non-animal health uses. (Holmes Decl., Ex. A ¶ 12.)

The Compound Patent. Another patent in Plaintiffs' portfolio, which covers the chemical compound fipronil itself, is not being asserted against the Defendant. U.S. Patent No. 5,232,940 ("the '940 Patent"), entitled "Derivatives of N-phenylpyrazoles," was issued on August 3, 1993. ('940 Patent, Ex. D.) The patent is relevant here because its expiration on August 3, 2010 is the deadline against which this lawsuit is running. (Holmes Decl., Ex. A ¶ 11.) Defendant plans to begin to sell infringing product on or about August 4 upon the expiration of the compound patent, even though they will infringe the '010, '743 and '943 Patents. (*Id.* ¶ 35.)

### III. The Fipronil Manufacturing Process

Fipronil is sold and used as "fipronil technical material," which must meet exacting EPA specifications that limit the amount of impurities that can be present in the fipronil used for commercial products. (Id. ¶ 9.) Certain of these impurities are difficult, sometimes impossible, to remove in a commercially viable way without also removing or significantly reducing the fipronil itself. (Sukopp Decl., Ex. C ¶¶ 10, 14-17.)

Fipronil is also difficult to manufacture, involving up to six complex steps, each with its own set of complications. (Id. ¶ 11.) For example, reagents and intermediates used throughout the manufacturing process are highly corrosive, toxic, volatile, and difficult to handle safely, and can quickly wear down or damage standard equipment and facilities. (Id.) Because of these complications and others, only a limited number of fipronil

manufacturing methods are technically viable, and fewer still are economically viable on a commercial scale. (*Id.* ¶¶ 10-11, 14-17, 19.)

Through substantial investments in research, development, and commercialization, BASF<sup>1</sup> has developed processes for manufacturing fipronil that are sufficiently safe, efficient, and scalable to profitably supply the mass market. (Holmes Decl., Ex. A ¶¶ 38-39.) To protect these investments, BASF has obtained patents, *e.g.*, the '943 Patent, covering various aspects of the fipronil manufacturing process. (*Id.*) The development of these manufacturing processes has been fundamental to fipronil's success because they make large-scale production economically viable. (Sukopp Decl., Ex. C ¶ 19.) BASF is not aware of any commercially viable, industrial-scale manufacturing process for fipronil technical material that would not infringe Plaintiffs' process patents if practiced in the United States. (*Id.* ¶¶ 19-24.)

#### IV. Plaintiffs' Successful Products Based on the Patents-in-Suit.

BASF Corp.'s fipronil-based branded products include Termidor SC®, Termidor 80 WG®, and Perimeter *Plus*<sup>TM</sup>. (Holmes Decl., Ex. A ¶¶ 15, 18.) The products have been enormously successful commercially. (*Id.* ¶¶ 16-22.)

With total net U.S. sales of tens of millions of dollars in 2008 and 2009, Termidor® has become the best selling termiticide brand in the United States since its introduction in 2000. (*Id.* ¶¶ 16, 21.) It is also the most effective; studies show that, when properly applied, it is nearly 100% effective in killing termite populations within three months. (*Id.*  $\P$  16.)

Termidor® had a 65% marketplace share of U.S. sales for termiticides in 2008, and an estimated 66% in 2009. (*Id.* ¶ 22.) Its nearest competitor had a marketplace

This includes not only BASF, but also the corporate entities from whom BASF purchased the fipronil business.

share of less than 5% in 2008 and 5% in 2009. (*Id.*) BASF Corp.'s sales of Termidor® products in the United States contributed tens of millions of dollars to BASF Agro B.V.'s gross profits in 2008 as well as in 2009. (*Id.*)

Not only is Termidor® enormously successful in its own right, but so too is BASF's proprietary Perimeter *Plus* method for its use. (*Id.* ¶¶ 19-20.) This brand name treatment method, which is the subject of the Perimeter Use Patents and is described in EPA-approved Termidor® Master Labels, involves creating a treatment zone around a structure's perimeter by applying Termidor®. (*Id.*; Davis Decl., Ex. B ¶¶ 5-7, 16.)

Just as Termidor® is the leading termiticide product in the U.S.,

Perimeter *Plus*<sup>™</sup> is the leading treatment method. (Holmes Decl., Ex. A ¶¶ 19-20.) In states where permitted by law, nearly 90% of Termidor® sales use the Perimeter *Plus*<sup>™</sup> method.

(*Id.* ¶ 19.) Because of its cost effectiveness and ease of use, BASF Corp.'s distributors and customers, including Orkin and Terminix, highly value the Perimeter *Plus*<sup>™</sup> brand and actively promote it. (*Id.* ¶ 20.)

Plaintiffs have invested tens of millions of dollars to innovate and build the premium name brands Termidor® and Perimeter*Plus*™ in the United States, including by investing in sophisticated marketing plans, creating a customer-valued service organization, and forging deep relationships with agents, distributors and end-users. (*Id.* ¶¶ 38-39.)

BASF's dedication to research, development, commercialization, marketing and service has earned it a reputation as a successful innovator in the insecticide field. (*Id.* ¶ 40.)

#### V. Defendant's Infringement of Plaintiffs' Patents.

There is little dispute that Defendant is and has been making meaningful preparation for engaging in activities – including importing, marketing, selling and distributing fipronil technical materials or fipronil-based products – that will infringe the

patents-in-suit. (*Id.* ¶¶ 27-35.) Defendant has taken concrete steps towards this end, and Plaintiffs expect infringing activities to begin in early August 2010. (*Id.*) Defendant's recent interactions with BASF and with BASF's customer demonstrate clearly that it intends to infringe the patents-in-suit by entering the U.S. market. (*Id.*) These include:

- In a letter dated January 28, 2010, in connection with Cheminova A/S's petition to the EPA to register "Cheminova Fipronil Technical" material, Defendant offered to pay BASF for its reliance on data that BASF earlier submitted to the EPA for fipronil products. (*Id.* ¶ 28.) This offer to pay was made pursuant to EPA regulations, which permit an entity seeking to register a pesticide to rely on data that has been previously submitted to the agency for a product with a substantially identical composition, so long as the subsequent applicant makes an offer to pay compensation to the original submitter of the data. (*Id.*) Companies do this, particularly companies selling generic products, rather than incurring the substantial expense and investing the time required to attempt to perform and rely on their own studies, which may or may not get approved. (*Id.*)
- In a letter dated March 15, 2010, Defendant again offered to pay BASF for its reliance on data that BASF earlier submitted to the EPA, now in connection with an EPA registration of its own "fipronil-containing end-use product." (Id. ¶ 29.) In both this letter and the January 28, 2010 letter, Defendant indicated it was using the faster "cite-all" method of data support under the EPA regulations, which allows Defendant to rely on all of BASF's previously submitted studies for a substantially identical composition and thereby attempt to gain EPA approval more quickly. (Id. ¶ 30.)
- In or about late March 2010, Defendant informed one of BASF's larger distributors of Termidor®, based in Austin, Texas, that it expected to offer an alternative, generic fipronil end-use product by this fall. (*Id.* ¶ 31.)
- On March 17, 2010, Martin Petersen, Defendant's President and CEO and Regional President of Cheminova A/S for North America, called Nevin McDougall, BASF's Group Vice President for North America, and stated that Cheminova would "invalidate" BASF's use patents, *i.e.*, the '010 and '743 patents, unless BASF agreed to license them to Cheminova. (*Id.* ¶ 32.) By this statement, Mr. Petersen threatened imminent litigation and admitted that Defendant plans to offer for sale in the United States products that would infringe the '010 and '743 patents unless they were deemed to be invalid

<sup>&</sup>lt;sup>2</sup> See FIFRA § 3(c)(1); 40 CFR § 152.86.

(which they are not) or Plaintiffs agreed to relinquish their legal right to be the exclusive provider of their patented products (which we do not intend to do). (*Id.*)

#### **QUESTION PRESENTED**

Should this Court grant a preliminary injunction to prevent Defendant's imminent and/or current infringement of Plaintiffs' valid and enforceable patents?

#### **ARGUMENT**

Federal courts have authority to "grant injunctions in accordance with the principles of equity to prevent the violation of any right secured by patent, on such terms as the court deems reasonable." 35 U.S.C. § 283. This authority extends to the prevention of future infringement that may not yet have occurred at the time the complaint was filed. *See, e.g., Glaxo v. Novapharm*, 110 F.3d 1562, 1570-71 (Fed. Cir. 1997) ("A patentee may seek a declaration that a person will infringe a patent in the future."). If a defendant "ha[s] taken 'concrete steps' (or, to put it another way, ha[s] made 'meaningful preparation') with intent to engage in potentially infringing activities," a court may properly adjudicate a declaratory judgment action to prevent future infringement. *Sierra Applied Sci., Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1378 (Fed. Cir. 2004) (citing *Lang v. Pacific Marine & Supply Co.*, 895 F.2d 761, 763-65 (Fed. Cir. 1990)).

Courts regularly grant preliminary injunctions upon an appropriate showing. See, e.g., Abbott Labs. v. Sandoz, Inc., 544 F.3d 1341 (Fed. Cir. 2008); Purdue Pharma L.P. v. Boehringer Ingelheim GMBH, 237 F.3d 1359, 1368 (Fed. Cir. 2001). A preliminary injunction carries particular importance in the patent context, because without the power to obtain an injunction, "the right to exclude granted by the patent would be diminished." Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1577-78 (Fed. Cir. 1983), cert. denied, 464 U.S. 996 (1983).

The "standards applied to the grant of a preliminary injunction are no more nor less stringent in patent cases than in other areas of the law." *H.H. Robertson, Co. v. United Steel Deck, Inc.*, 820 F.2d 384, 387 (Fed. Cir. 1987), *abrogated on other grounds by Markman v. Westview Instruments Inc.*, 52 F.3d 967 (Fed. Cir. 1995).

[A party may obtain a] preliminary injunction if it can succeed in showing: (1) a reasonable likelihood of success on the merits; (2) irreparable harm if an injunction is not granted; (3) a balance of hardships tipping in its favor; and (4) the injunction's favorable impact on the public interest.

Amazon.com Inc. v. Barnesandnoble.com, Inc., 239 F.3d 1343, 1350 (Fed. Cir. 2001).

Plaintiffs succeed in showing each.

# I. Plaintiffs Are Likely to Succeed on the Merits of Their Claims.

To demonstrate a reasonable likelihood of success, Plaintiffs must show that, in light of the presumptions and burdens that will inhere at trial, they will likely prove Defendant infringes at least one valid and enforceable patent claim. *See Abbott Labs. v. Andrx Pharm., Inc.*, 473 F.3d 1196, 1201 (Fed. Cir. 2007). At this preliminary stage, Plaintiffs need not prove infringement beyond all question; we need only show evidence of a "reasonable probability" of infringement. *H.H. Robertson*, 820 F.2d at 387. Plaintiffs easily satisfy this standard.

#### A. Defendant Will Infringe the Patents-in-Suit

# 1. Defendant Will Induce Infringement of the '010 and '743 Use Patents.

An entity is liable as an infringer when that entity "actively induces infringement of a patent." 35 U.S.C. § 271(b). In order to demonstrate inducing infringement, the patentee must show that the infringer is actively and knowingly aiding and abetting direct infringement by another person or entity. *Cross Med. Prods., Inc. v. Medtronic Sofamor Daniek, Inc.*, 424 F.3d 1293, 1312 (Fed. Cir. 2005).

By contacting Plaintiffs' Termidor® distributor to offer a generic fipronil termiticide by fall of 2010 while threatening to invalidate Plaintiffs' Perimeter Use Patents,

Defendant itself has tacitly admitted that it will induce infringement of the '010 and '743 Patents.

Plaintiffs believe that, when Defendant's already-submitted EPA master label becomes public (or is produced in this case), it will show that Defendant substantially copied Plaintiffs' pre-existing

Master Label for Termidor® and its patented Perimeter Plus<sup>TM</sup> method. (Davis Decl., Ex. B ¶¶

20-22.)

On information and belief, the copied Termidor® Master Label will instruct

Defendant's end-use customers to use Defendant's fipronil termiticide in a way that infringes the '010 and '743 patents. (*Id.*) BASF declarant, Dr. Robert W. Davis, provides a comprehensive analysis of exactly how the copied Termidor® Master Label's EP/LI (Perimeter *Plus* TM) method will satisfy each element of Claims 6 and 21 of the '010 Patent and Claim 2 of the '743 Patent. (*Id.* ¶ 16-32.) Indeed, Defendant could not, as a practical matter, enter the market with a product that did not provide an EPA master label allowing application of fipronil using the methods claimed in the '010 and '743 Patents. (*Id.* ¶ 21.) The cost savings, time savings, and ease of use associated with these methods of use -- along with the termite control market's now settled expectation that such methods of use are available -- are so significant that a fipronil-based product that did not employ those methods would not be commercially attractive to Defendant's distributors and customers. (*Id.*)

Providing customers with instructions on using a product in an infringing manner is strong evidence of inducement. *See MEMC Elec. Materials, Inc. v. Mitsubishi Materials Silicon Corp.*, 420 F.3d 1369, 1379 (Fed. Cir. 2005) ("Evidence of active steps taken to

encourage direct infringement, such as advertising an infringing use or instructing how to engage in an infringing use, show an affirmative intent that the product be used to infringe.") (internal citation omitted); *Metabolite Labs. Inc. v. Lab. Corp. Am. Holdings*, 370 F.3d 1354, 1365 (Fed. Cir. 2004) (finding active inducement based on defendant's publications describing and promoting use of patented method); *Minn. Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1305 (Fed. Cir. 2002) (finding inducement where defendant supplied infringing products to customers with instructions of use). Indeed, numerous decisions find active inducement where a defendant (selling products capable of either innocent or infringing use) provides through labels, advertising, or other sales methods, instructions and directions as to the infringing use. *See, e.g.*, *Biotec Biologische Naturverpackungen GmbH & Co. v. Biocorp., Inc.*, 249 F.3d 1341, 1351 (Fed. Cir. 2001); *Mentor H/S, Inc. v. Med. Device Alliance, Inc.*, 244 F.3d 1365, 1379 (Fed. Cir. 2001).

# 2. Defendant Will Infringe the '943 Patent By Selling Fipronil Manufactured By a Patented Process.

United States a product which is made by a process patented in the United States shall be liable as an infringer." The act that constitutes infringement is not the actual practicing of a patented process, but is the mere sale, offer for sale, or use of a product manufactured by a patented process. See Bio-Tech. Gen. Corp. v. Genentech, Inc., 80 F.3d 1553, 1560-61 (Fed. Cir. 1996).

Plaintiffs believe Defendant will sell, offer for sale, and use in the United States fipronil technical material that has been manufactured abroad and imported into the United States. (Holmes Decl., Ex. A ¶¶ 24, 28.) Plaintiffs believe that Defendant's foreign source will make fipronil using an "oxidation route" manufacturing process in which the final step to make

fipronil practices a process recited in one or more of Claims 1, 2, 3, 5, and 24 of the '943 Patent, Ex. E. (Sukopp Decl., Ex. C ¶¶ 20-24.)

Claim 1 literally covers a process to oxidize a group of compounds recited in formula (II), which includes a Sulfide compound, to make a group of compounds recited in formula (I), which includes fipronil, with trifluoroperacetic acid (TFPA) in the presence of a corrosion inhibitor. (*Id.* ¶ 23.) Claim 2 literally specifies that the TFPA of Claim 1 is formed by reacting trifluoroacetic acid (TFA) with hydrogen peroxide, and Claim 24 literally covers the formation of fipronil specifically from the Sulfide per the process of Claim 2. (*Id.*) Finally, Claims 3 and 5 literally cover the process of Claim 1 with either a boric acid or alkali borate salt corrosion inhibitor. (*Id.*)

If, as Plaintiffs believe, Defendant's source of fipronil manufactures fipronil using a reaction process according to Claims 1, 2, 3, 5, and 24, (*id.* ¶¶ 20-24), Defendant's sale, offer for sale, or use in the United States of this non-BASF fipronil will infringe the '943 Patent under 35 U.S.C. § 271(g).

Additionally, Defendant will contribute to and induce the infringement of the '943 patent under 35 U.S.C. §§ 271(b) and (c) by selling its non-BASF fipronil to customers who, by using the fipronil, become direct infringers under 35 U.S.C. § 271(g).

#### B. Plaintiffs' Patents Are Not Invalid or Unenforceable

On infringement, Plaintiffs need only prove that one claim is infringed. To prove invalidity, Defendant must prove that every one of the infringed claims is invalid.

By statute, each claim of Plaintiffs' patents is presumptively valid. 35 U.S.C. § 282. To defeat an injunction on these grounds, Defendant must show that it is likely to succeed in providing invalidity or unenforceability of the patents-in-suit. *Abbott Labs.*, 473 F.3d at 1201 (citation omitted). If Defendant fails to do so, then the very existence of the

patents satisfy the issue of validity, and the Plaintiffs need not make any showing regarding validity to be entitled to relief. *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed. Cir. 1998).

Though a sufficient basis for the issuance of a preliminary injunction, the Court here need not rely on the presumption of validity. The validity of the patents-in-suit is confirmed by the remarkable commercial success of fipronil, Termidor®, and PerimeterPlus™. (Holmes Decl., Ex. A ¶¶ 16-24.) See, e.g., Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1275 (Fed. Cir. 1995) (emphasizing commercial success of patented product and failure of others to achieve invention in finding nonobviousness). As noted, Termidor® and PerimeterPlus™ are both market-leading products – one the bestselling and most effective termiticide sold in the United States, and the other, its most successful method of use. (Holmes Decl., Ex. A ¶ 16-20.) Furthermore, Plaintiffs believe Defendant directly copied Termidor® with a copycat fipronil-based product and copied Termidor®'s master label, (Sukopp Decl., Ex. C ¶¶ 20-24; Davis Decl., Ex. B ¶¶ 20-22), and "[c]opying is an indicium of nonobviousness, and is to be given proper weight." Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 679 (Fed. Cir. 1988) (citing Windsurfing Int'l, Inc. v. AMF, Inc., 782 F.2d 995, 1000 (Fed. Cir. 1986) ("the district court correctly noted that copying the claimed invention, rather than one within the public domain, is indicative of non-obviousness")).

# II. Plaintiffs Will Be Irreparably Harmed Absent A Preliminary Injunction.

As detailed in the declaration of Keith Holmes, the Business Unit Manager of the Pest Controls Solutions business of BASF Corporation, Defendant's infringing activities will undermine the purpose of the patent laws, irreparably injure Plaintiffs and by materially and irreversibly eroding their sales, market share, prices, goodwill, and reputation, in ways that are impossible to quantify. (Holmes Decl., Ex. A ¶¶ 36-50.)

Plaintiffs have made very considerable and costly efforts innovating, developing, and marketing their patented products and the methods to manufacture and use those products, to establish their exclusive market position. (*Id.* ¶ 38-39.) Defendant will be able to piggy-pack off of BASF's investments and resources spent purchasing the fipronil business and further developing the market, thereby offering their copycat generic product at a significantly cheaper price. (*Id.* ¶ 41, 44-45.) This, in turn, will lead to price erosion, which, "is most likely to occur in cases like this one, in which no generic competitors have yet entered the marketplace, placing the patentee in an exclusive position." *Ortho-McNeil Pharm.*, No. 03-4678, 2009 WL 2182665, at \*10 (D.N.J. July 22, 2009).

Indeed, because Defendant's costs do not reflect Plaintiffs' significant investments, research and development costs, it is expected that Defendant will offer its infringing product at 40-60% less than BASF's Termidor product at the wholesale level. (Holmes Decl., Ex. A ¶ 44.) To stay competitive, BASF will be forced to lower its prices. (*Id.* ¶¶ 44-45.) Generic entry is likely to trigger pricing renegotiations with BASF's large customers. (*Id.* ¶ 45.) Once Plaintiffs are forced to lower their prices upon generic entry, it is virtually impossible that they will be able to raise them back to where they would have been, if they ultimately prevail in this case. (*Id.* ¶ 46.)

These market and pricing disruptions are also certain to threaten BASF's precious and hard-earned relationships with its customers, and its reputation as the technological and business leader of the termiticide market. (*Id.* ¶¶ 47-48.) *See Motorola, Inc. v. Alexander Mfg. Co.*, 786 F. Supp. 808, 815 (N.D. Iowa 1991) ("Money cannot

adequately compensate for injury to reputation."). Generic entry and the contentious pricing negotiations it will necessarily bring about with BASF's distributor-customers will also likely strain those relationships, which may well affect sales of other, non-fipronil products in ways that cannot be quantified.<sup>3</sup> (Holmes Decl., Ex. A ¶ 47.) *See Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975-76 (Fed. Cir. 1996) ("The market is rarely the same when a market of multiple sellers is suddenly converted to one with a single seller by legal fiat."); *Lifescan, Inc. v. Polymer Tech. Int'l Corp.*, No. C94-672R, 1995 WL 271599, at \*20 (W.D. Wash. Jan. 03, 1995) (finding plaintiff "is likely to lose goodwill with its customers because of the pricing difference between [plaintiff's and defendant's products.]"). This could naturally have spillover effects into its sales of other products. (Holmes Decl., Ex. A ¶ 47.) And ultimately, lost sales, price erosion, loss of goodwill, and lost profits are likely to have adverse effects on BASF's research and development budget going forward. (*Id.* ¶¶ 49-50.) *See, e.g., Ortho-McNeil Pharm. Inc. v. Barr Labs., Inc.*, 2009 WL 2182665, at \*10; *Bushnell, Inc. v. Brunton Co.*, 2009 WL 4251633 (D. Kan, Nov. 25, 2009).

These are precisely the types of injuries that courts have identified as constituting irreparable harm. *See, e.g., Sandoz, Inc.*, 544 F.3d at 1361-62 (lost market share, revenue loss, and price erosion supported irreparable harm finding); *Sanofi-Synthelabo, Inc. v. Apotex, Inc.*, 470 F.3d 1368, 1382 (Fed. Cir. 2006) (price erosion constituted irreparable harm); *Bio-Tech. Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1566 (Fed. Cir. 1996) (loss of goodwill supported preliminary injunction); *Bushnell, Inc. v. Brunton, Inc.*, No. 09-2009, 2009 WL 4251633, at \*20 (D. Kan. Nov. 25, 2009) ("Plaintiffs' evidence of reputational harm and loss of goodwill supports a finding of irreparable harm."); *Medco Research, Inc. v.* 

Indeed, upon generic entry, BASF's goodwill and reputation would be damaged by a change in its ability to offer its wholesale customers agency relationships, which earn them commissions, as opposed to distributor relationships, which only earn them resale margins. (Holmes Decl., Ex. A  $\P$  48.)

Fujisawa USA, Inc., No. 93-2705, 1994 WL 719220, at \*13 (N.D. Ill. Dec. 21, 1994) (competitor's entry would confuse customers and diminish goodwill).

Here, not only are these harms irreversible, but they are also nearly impossible to quantify. This is, in part, because the monetary harm caused by Defendant's infringement has not yet been realized and may not begin to be realized until after Defendant obtains regulatory approvals and enters the marketplace, which creates uncertainty with respect to the amount of any future damages calculation, and supports a finding of irreparable harm. *See, e.g., Ortho-McNeil Pharm., Inc. v. Barr Labs., Inc.*, 2009 WL 2182665, at \*10 (irreparable harm established where damages resulting from allowing a generic entry would not be readily and accurately quantifiable); *Medco Research*, 1994 WL 719220, at \*14 (irreparable harm established where "the difficulty of calculating damages for lost profits [with respect to a pharmaceutical] is especially difficult in light of the unpredictability of the FDA approval process").

## III. The Balance of Hardship Weighs in Plaintiffs' Favor.

Even where "neither party has a clear advantage" in the balance of hardships, it is appropriate that a preliminary injunction be entered. *Hybritech Inc. v. Abbott Labs.*, 849 F.2d 1446, 1457-58 (Fed. Cir. 1988). Here, however, the hardships plainly weigh in favor of Plaintiffs.

Defendants are not currently marketing fipronil-containing products in the United States, and, thus, face no harm to their businesses if the preliminary injunction is entered. Plaintiffs, by contrast, have a significant existing business, valuable brands, and a reputation as an innovator that have been built over a period of years. In situations such as these, where the patentee "stands to 'lose the value of its patent,' while [the accused infringer] 'would only lose the ability to go on to the market and begin earning profits

earlier,' the balance of hardships factor favors the grant of the preliminary injunction."

Ortho-McNeil Pharm., Inc. v. Mylan Labs. Inc., No. 04-1689, 2006 WL 3019689, at \*10-11

(D.N.J. Oct. 23, 2006) (citation omitted); see also Critikon, Inc. v. Becton Dickinson

Vascular Access, Inc., 28 U.S.P.Q.2d 1362, 1371 (D. Del. 1993) ("The hardship facing

[defendant] in delaying its entry into the market three to six months is not as severe as that faced by [plaintiff] by not being able to enforce its apparently valid patent, and the potential harm that will result to its reputation and goodwill as an innovator.")

#### IV. The Public Interest Supports Granting a Preliminary Injunction

The issuance of a preliminary injunction in this case would serve the most important public interest at stake, "the public interest in protecting rights secured by valid patents." *Hybritech Inc.*, 849 F.2d at 1458. This comports with the general rule in patent cases, where the public interest factor weighs in favor of granting a preliminary injunction to uphold the patent laws against infringers. *See H.H. Robertson*, 820 F.2d at 391 (noting "the 'protection of patents furthers a strong public policy ... advanced by granting preliminary injunctive relief when it appears that, absent such relief, patent rights will be fragrantly violated."). This arises from the profound interest in encouraging the development of new technologies:

One of the bases of intellectual property law is to give inventors an incentive to practice their talents by allowing them to reap the benefits of their labor. One of these benefits is the right to prevent others from practicing what they have invented. Otherwise, if inventors cannot depend on their patents to exclude others, we fear that research and development budgets in the science and technology based industries would shrink, resulting in the public no longer benefiting from the labors of these talented people.

E. I. du Pont de Nemours & Co. v. Polaroid Graphics Imaging, Inc., 706 F. Supp. 1135, 1146(D. Del. 1989), aff'd, 887 F.2d 1095 (Fed. Cir. 1989).

Nor is any public interest disserved by entering a preliminary injunction against Defendant. Whatever public interest there is in minimizing market disruption is best served by preliminary enjoining an infringing product. Such an injunction prevents consumers and others from coming to rely and depend on upon the availability of a product that will be subject to removal from the market once a final determination of infringement is made. See Solarex Corp. v. Advanced Photovoltaic Sys., Inc., 34 U.S.P.Q.2d 1234, 1241 (D. Del. 1995); Critikon, Inc., 28 U.S.P.Q.2d at 1371.

#### **CONCLUSION**

For the foregoing reasons, Plaintiffs' motion for a preliminary injunction should be granted.

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DATED: April 16, 2010 /s/1

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#### **CERTIFICATE OF SERVICE**

I hereby certify I electronically filed **PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR PRELIMINARY INJUNCTION** with the Clerk of Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants and the non-CM/ECF participants by United States first class mail, postage prepaid and addressed as follows:

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